

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

)	
IN RE: PHARMACEUTICAL)	
INDUSTRY AVERAGE)	MDL NO. 1456
WHOLESALE)	
PRICE LITIGATION)	
)	CIVIL ACTION: 01-12257-PBS
_____)	
)	
THIS DOCUMENT RELATES TO)	Judge Patti B. Saris
ALL ACTIONS)	
_____)	

STIPULATED PROTECTIVE ORDER GOVERNING
CONFIDENTIAL HEALTH INFORMATION

To adequately protect individually identifiable health information entitled to be kept confidential, it is, pursuant to the Court's authority under Rule 26(c) of the Federal Rules of Civil Procedure, and with consent of the parties, ORDERED:

1. **Definitions :**

(A) As used in this Order, the term **"party"** shall mean all named parties to any action in the above-captioned Multi-District Litigation (MDL), including any named party added or joined to any complaint in this action, as well as named parties to tag-along actions added to this litigation by the Judicial Panel on Multi-District Litigation.

(B) The term **"third-party"** shall mean any individual, corporation, other natural person or entity, or any state, federal, or local government agency, specifically including the United States Department of Health and Human Services.

(C) The term **"documents"** as used herein is intended to be comprehensive and includes any and all materials in the broadest sense contemplated by Rule 34 of the Federal Rules of Civil Procedure, and shall include all written, oral, recorded, or graphic

material, however produced or reproduced, including, but not limited to, all written or printed matter of any kind, computer data, all graphic or manual records or representations of any kind, and electronic, mechanical, or electric records or representations of any kind.

(D) As used in this Order, the term “**confidential health information**” means any document or information supplied in any form, or any portion thereof, that identifies an individual or subscriber in any manner and relates to the past, present, or future care, services, or supplies relating to the physical or mental health or condition of such individual, the provision of health care to such individual, or the past, present, or future payment for the provision of health care to such individual. These terms specifically include “protected health information” as such term is defined by the Standards for Privacy of Individually Identifiable Health Information, 45 C.F.R. Parts 160 and 164, promulgated pursuant to the Health Insurance Portability and Accountability Act of 1996. See 45 C.F.R. § 164.501 (“protected health information”) and 160.103 (“individually identifiable health information”). “Confidential health information” includes, but is not limited to, medical bills, claims forms, charge sheets, medical records, medical charts, test results, notes, dictation, invoices, itemized billing statements, remittance advice forms, explanations of benefits, checks, notices, and requests. “Confidential health information” also includes all notes, summaries, compilations, extracts, abstracts, or oral communications that contain, are based on, or are derived from confidential health information.

2. **General Provisions:**

(A) Production of Health Information That May Be Subject To The Privacy Act, 5 U.S.C. § 552a, to 45 C.F.R. §§ 164.102-164.534, or to 42 U.S.C. § 1306, or Other

Privacy Protections. Several subpoenas duces tecum have been served and will be served in the future in the above-captioned Multi-District Litigation (MDL) which may seek information and documents subject to the provisions of the Privacy Act, 5 U.S.C. § 552a, to the provisions of 45 C.F.R. §§ 164.102-164.534, or to the provisions of 42 U.S.C. § 1306, or there may be no waiver by the patient to produce the records to any entity outside of the subpoenaed party. In order to facilitate the production of these records and to protect their confidentiality, the subpoenaed parties are permitted to produce these documents to any party to the MDL in an unredacted form. Upon producing these documents, the producing party shall designate them as “confidential” in the manner set forth in paragraph II. B. below. All parties receiving these documents may use such designated records only for purposes of the above-captioned Multi-District Litigation and may disclose them to non-parties to this litigation only as specified within this Order and only if the nonparty signs the form of acknowledgment attached to this Order as set forth below.

(B) **Designation of Material Subject to this Protective Order.** To designate “confidential health information” material covered by this Protective Order, the producing party shall so designate, on the material itself, in an accompanying cover letter, or on a diskette cover by using the following designation: “CONFIDENTIAL HEALTH INFORMATION- SUBJECT TO PROTECTIVE ORDER.”

(C) **Scope of Order.** The terms and conditions of this Order shall govern all documents designated as confidential as set forth in section II. B. Should a document or record contain information that is protected under the terms and conditions of this Order

as well as the terms and conditions of any other Protective Order entered in the above-captioned MDL, the terms and conditions of this Order shall govern in the event of any conflict between the Orders.

III. **Provisions Governing Use and Disclosure of Confidential Health Information:**

(A) The parties may not use or disclose confidential health information for any purpose other than use in the above-captioned MDL.

(B) Subject to Paragraph III.C., confidential health information may be disclosed only to:

1. This Court and all persons assisting this Court in this action, including court reporters taking testimony involving such information, and necessary stenographic and clerical personnel;

2. Persons retained as consultants or experts for any party and principals and employees of the firms with which consultants or experts are associated;

3. Persons other than consultants or experts who are retained to provide purely administrative assistance to counsel for any party for the purpose of this action, including litigation support services and outside copying services;

4. Any person who may testify as a witness at a deposition, hearing, mediation, trial, or other proceeding in this action, and for the purpose of assisting in the preparation or examination of the witness, provided that counsel first comply with the requirements of Paragraph III. C. of this Order;

5. And other person hereafter designated by written stipulation of the parties and, if applicable, the third-party who produced or supplied the confidential health information, or by further order of this Court; and,

6. The parties, the parties' counsel and their partners, associates, paralegals, and clerical and support personnel.

(C) No confidential health information may be disclosed to any person pursuant to the provision of Paragraph III.B. of this Order unless counsel first informs such person that pursuant to this Order the material to be disclosed may only be used for purposes of preparing and presenting evidence in this litigation and must be kept confidential. No confidential health information may be disclosed to any person identified in subparagraphs III.B.2 through III.B.6 of this Order unless such person first is given a copy of this Order and advised that the information contained in the document is confidential health information and informed that an unauthorized disclosure of the information in the document may constitute a contempt of this Court. Each person to whom confidential health information is disclosed pursuant to Subparagraph III.B. of this Order shall execute a Certification in the form attached hereto as Exhibit A and shall agree to be bound by this Order prior to receiving any confidential health information. Copies of the executed Certifications, and a current log of the materials disclosed to each person executing a Certification, shall be retained by counsel for the party or parties who disclosed the confidential health information to such persons. Copies of all Certifications executed pursuant to this Paragraph shall be disclosed to the party or third-party who produced or supplied the confidential health information a) within thirty (30) days after the final resolution of this action (including resolution of all appellate proceedings), b) within thirty (30) days after settlement of this action, or c) on good cause shown.

(D) No person, firm, corporation, or other entity subject to this order shall give, show, disclose, make available, or communicate confidential health information to any person, firm, corporation, or other entity not expressly authorized by this Order to receive such confidential health information.

(E) **Confidential Health Information in Depositions.** Parties may show deponents designated confidential documents. However, efforts should first be made, if practicable, to conceal the identity of the subject of the record by coding the documents to substitute a numerical or other designation for the patient's name or other identifying information. The parties shall, within 30 business days after receiving a deposition, designate those pages of the transcript (and exhibits thereto) as confidential which contain any references to, or discussions confidential health information or individually identifiable health information. Until expiration of the 30-day period, the entire deposition will be treated as subject to protection against disclosure under this Protective Order. Confidential health information within the deposition transcript must be designated by underlining the portions of the pages that are confidential and marking such pages with the following legend: "CONFIDENTIAL HEALTH INFORMATION SUBJECT TO PROTECTIVE ORDER." When such designation is made, the confidential portions and exhibits shall be filed under seal separate from the portions and exhibits not so marked. The terms and conditions of this Order shall apply to all such designated portions of any deposition transcript.

(F) **Use of Confidential Health Information in Court Filings.** In the event any party wishes to use confidential health information in any affidavits, briefs, memoranda of law, exhibits to motions, or other papers filed in Court in this action, such party shall take appropriate steps to safeguard such confidential health information in

documents filed with the Court, which steps may include redaction. In the event this Court wishes to review the redacted material, this Court may review the redacted material *in camera* or order that the documents containing confidential health information be filed under seal. Alternatively, the parties may file such affidavits, briefs, memoranda of law, exhibits to motions, or other papers under seal with this Court. The Clerk of Court shall accept for filing under seal any documents or filings so marked by the parties pursuant to this paragraph.

(G) **Confidential Health Information in Open Court.** The procedures for use of documents designated as containing confidential health information during any hearing or the trial of this matter shall be determined by the parties and the Court in advance of the hearing or trial. The parties shall consider redacting confidential documents to remove individual patient identifiers, request the Court to submit such documents under seal, code the documents to substitute a numerical or other designation for the patient's name or other identifying information, request that any exhibit be placed under seal, introduce summary evidence where practicable which may be more easily redacted, and assure that all Social Security and HIC numbers associated with the names of individual patients have been removed. No party shall disclose designated documents containing confidential health information in open Court without a prior court order.

IV. **Destruction of Confidential Health Information At Completion of Litigation:**

(A). Within sixty (60) days after the final resolution of the above-captioned action, including resolution of all appellate proceedings, all documents and copies of documents produced or supplied pursuant to a third-party subpoena which are designated

as containing confidential health information, as well as all notes, memoranda, and summaries taken or made of such documents that contain confidential health information, shall be either returned to the producing party or destroyed.

(B) All counsel of record who received documents shall certify compliance herewith and shall deliver the same to the producing party not more than sixty (60) days after the final resolution of this action. The return of documents or certifications of destruction relating to documents produced by the United States shall be provided to the U.S. Department of Health and Human Services, Office of General Counsel, Centers for Medicare & Medicaid Division.

V. **Miscellaneous Provisions:**

(A) **No Waiver.** The failure to designate any materials as provided in paragraph II.B shall not constitute a waiver of the assertion that the materials are covered by this Protective Order.

(B) **Third-Party Request or Demand for Disclosure.** Should any party bound by this Order receive a subpoena, civil investigative demand, or other process from a third-party seeking, requesting, or requiring disclosure of confidential health information in any form, such person shall give notice immediately to the producing party so that the producing party may seek appropriate relief, if any. Notice shall be made within ten (10) days of the request for production and shall be in writing. Notice to the United States shall take the form of written notification to U.S. Department of Health and Human Services, Office of General Counsel, Centers for Medicare & Medicaid Division. No person bound by this Order who receives a subpoena, civil investigative demand, or other process from a third-party seeking, requesting, or requiring the disclosure of confidential health information shall produce or disclose such documents or

information unless and until a) ordered by a court having competent jurisdiction, or b) such production or disclosure is in accordance with the provisions herein and is expressly consented to by the producing party.

(C) **The Application of Other Privacy Provisions of Law.** Notwithstanding any provision of this Order to the contrary, in accordance with any applicable Federal, State, or local laws that afford heightened protection to certain categories of confidential health information, including, but not limited to, records or diagnosis or treatment for alcohol or substance abuse, certain sexually transmitted diseases such as HIV/AIDS, mental health, and research pertaining to genetic testing, the producing party may completely exclude from production any information afforded heightened protection by such Federal, State, or local laws.

(D) Nothing in this Order shall affect the rights of the parties or third-parties to object to discovery on grounds other than those related to the protection of confidential health information, nor shall it preclude any party or third-party from seeking further relief or protective orders from this Court as may be appropriate under the Federal Rules of Civil Procedure.

(E) Any person requiring further protection of confidential health information may petition this Court for a separate order governing the disclosure of its information.

(F). The provisions of this Order shall survive the conclusion of this action.

SO ORDERED, this _____ day of _____ 2004.

Patti B. Saris United States District Judge

CERTIFICATION - EXHIBIT A

I certify that I have read the attached Stipulated Protective Order Governing Confidential Health Information in *In Re: Pharmaceutical Industry Average Wholesale Price Litigation*, MDL No. 1456, Civil Action No. 01-12257-PBS, dated _____, 2004 (the Order), and I agree that I will not use or disclose Confidential Health Information or Individually Identifiable Health Information for any purpose other than this litigation and that, within sixty days (60) after the final resolution of this action, I will either return all Confidential Health Information to the United States or destroy such Confidential Health Information. I will otherwise keep all Confidential Health Information in accordance with this Order. I agree that the United States District Court for the District of Massachusetts has jurisdiction to enforce the terms of the Order, and I consent to jurisdiction of that Court over my person for that purpose. I will otherwise be bound the strictures of the Order.

Dated: _____
[Print Name]
[Company]
[Address]